K113681

JAN 11 2012

510(k) Summary

Submitter	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Person	Amber R. Johnson
Phone Number	763-494-2643
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Date Prepared	December 14, 2011
Device Trade Name	Gladiator PTA Balloon Dilatation Catheters
Common Name	Percutaneous Transluminal Angioplasty Dilatation Catheter
Device Classification	Class II 21 CFR 870.1250 Product Code: LIT, DQY

Predicate Device

Mustang PTA Balloon Dilatation Catheters

Device Description

The Boston Scientific Gladiator™ Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is an Over-the-Wire (OTW) balloon catheter with a dual lumen shaft design. One lumen marked "WIRE" is used to pass the catheter over 0.035" (0.89mm) guidewires. The second lumen marked "BALLOON" communicates with the balloon and is used to inflate and deflate the balloon during the procedure. The guidewire lumen and the balloon lumen terminate at the proximal end of the catheter in a Y-connector manifold with luer lock fittings. There are two radiopaque markerbands located under the balloon shoulders to aid in positioning the system during the procedure. A coating is applied to the balloon to enhance insertion and withdrawal performance. The tip of the catheter is gradually tapered to facilitate advancement of the catheter through the stenosis.

The Gladiator Balloon Dilatation Catheter will be available with balloon diameters 3.0 mm to 12.0 mm, balloon lengths 20 mm to 100 mm, and with shaft lengths of 40 cm and 75 cm.

Indications for Use

The Gladiator Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The Gladiator Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Substantial Equivalence

The Gladiator PTA Balloon Dilatation Catheters design, materials, and intended use are substantially equivalent to the predicate device Mustang PTA Balloon Dilatation Catheters (K103751).

Comparison of Technological Characteristics

The Gladiator PTA Balloon Dilatation Catheter incorporates substantially equivalent device design and materials, packaging design and materials, fundamental technology, sterilization processes and intended use as those featured in the Boston Scientific predicate device Mustang PTA Balloon Dilatation Catheters (K103751).

Comparison to Predicate Device

Characteristic	Mustang predicate
Manifold Hub	Same material. Different colorant/additive. Same design serving same function.
Bumper Tip	Same material. Different colorant. Same design serving same function.
Strain Relief	Same material. Same design serving same function.
Proximal Dual Lumen Shaft	Same material. Same design serving same function.
Proximal Shaft Outer Diameter	Same shaft outer diameters.
Balloon	Same balloon material. Same design serving same function and fundamental technology.
Balloon Protector	Same material and similar design serving same function.
Pinch-off Tube	Same material. Same design serving same function.
Markerbands	Same component serving same function.
Coating	Same coating serving same function.
Packaging Design	Similar design serving same function. Same carrier tube materials. Different configuration.
Sterilization Method	Same method.
SAL	Same level of assurance.
Lumens	Same lumens serving same function.
Recommended Guidewire	Same compatibility.
Balloon Diameters	Same balloon diameter serving same function.
Balloon Lengths	Within range of predicate serving same function.
Effective Length	Within range of predicate serving same function.
Rated Burst Pressure (RBP)	Same Rated Burst Pressure (RBP).

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Performance Data

Biocompatibility testing, bench testing, and sterilization qualification were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during testing.

The following biocompatibility tests were completed on the Gladiator PTA Balloon Dilatation Catheter:

- MEM Elution Cytotoxicity
- Guinea Pig Maximization Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Materials Mediated Rabbit Pyrogen
- Bacterial Mutagenicity (Ames Assay)
- Mouse Lymphoma Assay
- Hemolysis Direct Contact and Extract
- Partial Thromboplastin Time
- In Vitro Hemocompatibility Assay
- Complement Activation
- USP Physicochemical
- Natural Rubber Latex

Conclusion:

Based on the indications for use, technological characteristics, safety and performance testing, the Gladiator Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific Mustang Balloon Dilatation Catheters (K103751).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 11 2012

Boston Scientific
c/o Ms. Amber Johnson
One Scimed Place
Maple Grove, MN 55311

Re: K113681
Trade/Device Name: Gladiator Balloon Dilatation PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: LIT, DQY
Dated: December 14, 2011
Received: December 15, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Killelea

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K113681

Device Name **Gladiator™ PTA Balloon Dilatation Catheters**

Indications for Use

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Prescription Use __X__ (Per 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use____ (Per 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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